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A PROGRESS REPORT ON RISK ANALYSIS

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Ludwig Benner, Jr.

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### PREFACE

The climate in which "safety" decisions are being made in the public and private sectors of our society has changed dramatically in the last decade. In this new climate, decision makers are confronted by an intensifying demand for a better understanding of the safety and health risks accompanying certain activities, and for a more rational consideration of these risks in the decisions made. The technological capability for satisfying this demand is developing rapidly. These capabilities, in turn, will have a profound influence on our society and its operation. The purpose of this paper is to briefly review some of the reasons behind the interest in risk analysis, to highlight the technological developments affecting risk analysis capabilities, and to speculate on the effects these activities portend for persons affiliated with chemicals.

### RISK ANALYSIS: WHY BOTHER?

"Great deeds are wrought at great risks." Herodotus' observation reflects a viewpoint that over the centuries has influenced many deeds and decisions. Individually and collectively, persons have taken and will continue to take risks in connection with great deeds -- and middle-sized deeds, and small deeds, too. We take risks because we want to achieve some end. But we do not know with certainty what the future holds in store for us. So, as we strive to achieve our ends, we recognize that things can go wrong. In our modern, complex and highly interrelated activities, uncertainties affect -- and sometimes determine -- the course of events. Most persons recognize the non-zero probability of achieving the ends we seek without perturbation or interference, and are prepared to take some chances.

Events in recent years, particularly since World War II, have disclosed circumstances which compel a reexamination of the greatness of some deeds and the nature of the risks which should be taken. We have growing evidence that certain deeds can adversely affect the present or future safety of large numbers of people, or possibly even the future habitability of the planet on which we live. Recall, for example, the recent histories of thalidomide, DDT, kepone, vinyl chloride, or any of the dozens of other chemicals in the news in recent years, and you can appreciate the apprehension of laymen. Or consider the concerns about plutonium contamination, which has the potential for threatening large areas of the planet for many years. The controversy is not spurious; it raises the most basic questions of personal beliefs and human values -- the kind and degree of risk and uncertainty that any individual is willing to accept in his daily life.<sup>1</sup> Add the "spaceship Earth" perception -- one of the major legacies of the space age,<sup>2</sup> -- and the resultant need to achieve a global equilibrium of our activities<sup>3</sup> and it becomes easy to recognize why mankind is increasingly concerned about the long-term future.

To make better judgments about such risks and uncertainties for both the short and long term future, the individual wants to know more about

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\*The author is Chief, Hazardous Materials Division, National Transportation Safety Board. The views expressed are those of the author, and do not necessarily represent the views of the National Transportation Safety Board.

them. In the light of recent experiences with personal and global threats to safety and health, an increasing number of individuals have lost confidence in traditional approaches and decision processes for such risk taking. They demand that certain types of these risks be better understood and more deliberately and extensively evaluated before any more "great deeds" are done. <sup>analytical</sup> Before an energy program can be supported, the risks that accompany the nuclear option must be identified and evaluated. Safety risks of liquefied natural gasses are subjected to similar scrutiny by those who might be adversely affected by the decisions. Similar demands are arising in the area of chemical safety, as has been widely reported in the media.<sup>4</sup>

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Concerns about the acceptability of risks are being reflected in political decisions. Legislation such as the Toxic Substances Control Act and the Resource Conservation and Recovery Act, passed in 1976, and the Hazardous Materials Transportation Act of 1974 can be directly attributed to this influence. It is interesting to note that Congress has been viewing these concerns in terms of "unreasonable risk" to safety and health or property.<sup>5</sup> Environmental legislation at both the Federal and State levels has also proliferated, for largely the same reason. The concerns also appear to be the principal motivation of many "public interest" environmental, safety and health action groups and activities.

These events lead inexorably to the conclusion that traditional approaches to analyzing, assessing and acting on safety and health risks are inadequate in today's climate of concern for the future. The traditional approaches were to examine accidents or health problems, seek out their causes, and correct them. This was done on an ad hoc, usually uncoordinated basis by numerous, highly motivated persons using retrospective methods and techniques. Occasionally, as with cancer research, large amounts of resources were brought to bear on these problems. The approaches did "reduce accidents," "save lives," and achieve "economic gain of substantial proportions."<sup>6</sup>

In the pre-nuclear, pre-space eras, this retrospective ad hoc approach probably satisfied public concerns. Doing one's best was good enough, even for the public. But the nuclear and space programs, and others, required a shift from the "fly-fix-fly" trial and error, post facto methods to a "safe-first-time" predictive approach, because of the concern over the global or national consequences of accidents, or uncontrolled risk taking.

Further intensifying the demand for predictive approaches to safety and health decisions was the emergence of the "management by objectives" philosophy and methods in organizations of all kinds. The need for a predictive, quantitative statement of the safety objectives of the organization simply could not be satisfied by the traditional approaches. The same need is emerging in the health field. In the competition for limited resources, the ad hoc arguments were not very persuasive in capturing a significant share of scarce resources. The emphasis was on MBO growth and operating investments.<sup>7,8,9</sup>

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Concurrently, during the 1960's particularly, safety research began to cast doubts on the quality of safety efforts of the past. The need for the application of better "science" to safety problems surfaced increasingly during this period.<sup>7,8,9</sup> The entire climate of safety research, along with changes in funding levels, was changing at an accelerating pace. Arguments about "how safe is safe enough" <sup>10</sup> began to surface and get attention.

The first persuasive, comprehensive evidence that risk levels and "safe enough" might eventually be quantified emerged from Starr's work in the late 1960's.<sup>11</sup> There seems little room for controversy that his work gave credibility to the notion that rational "safety" and "health" objectives for decision making were potentially attainable, using a risk-based approach to the problems. When this work came to my attention, a way to resolve the dilemmas described above became apparent, and my frustrations over my inability to fit safety decisions into a common framework with other decision tasks suddenly evaporated. Others have shared similar experiences with me.

Much has happened since then.

RISK ANALYSIS: WHAT IS IT? *But before I do, let's talk about what RA is and is not.*

Many analytical efforts have been labeled "risk analyses." Not all have been. You should be aware of the differences.

A bona fide risk analysis has <sup>at least</sup> ~~several~~<sup>3</sup> attributes. First, it is process-oriented. That is to say, it deals with a flow of events in a disciplined, orderly way. It breaks down the process or mechanisms by which the desired ends will be achieved, and by which the course of events can be transformed into an undesired harmful outcome. Second it identifies the "targets" of the potential harm that may occur during the course of the activity. Third, it provides a quantitative estimate of the probabilities associated with the different harmful outcomes that are being considered, and relates them to operation of the activity, i.e., the exposures. ~~Fourth~~<sup>Here</sup>, it should permit the identification of the change in the risks that could be achieved by the introduction of certain actions or controls, if that is the purpose of the analysis.

The purposes of risk analyses vary widely. In the safety and health areas, the purposes include the identification of ways harm can occur, as well as the probable harm that occurs. Increasingly they are used for risk assessments in decision making, as will be seen below.

The results of risk analyses are expressed in divergent ways, also. The harmful or beneficial outcomes relative to undesired ends may be identified as numbers of deaths, reduced life expectancies, bed days, infections, etc. These losses are related to the operation of the activity in terms of the duration or output measure of the activity. Note that it is not necessary to reduce the risk estimates to economic terms to arrive at the value judgments exercised in the use of the estimates. ~~Expression~~ of risk estimates is not without its problems.<sup>12</sup> However, Starr's work showed a way to present both comparative and absolute risk levels, using time -- the one factor common to all activities and processes -- and fatalities, another factor common to all persons, for his purposes.

As a methodology, risk analysis has limitations. One report<sup>13</sup> stated the situation this way:

"The panel concluded that the greatest utility of the methodology, and perhaps the only practical one, lies in answering specific questions with output of a specific predetermined nature."

It is vital to recognize that risk must be related to the other factors to be useful. Risk analysis is not risk assessment. Risk analysis describes the risks; risk assessment is the process of giving weight to the risks for deciding a course of action in the face of value or other conflicts confronting the decision maker.

Risk analysis is more than a statistical or reliability numbers game. It does not rely on statistical inferences, nor does it rely on engineering

~~proofs~~ estimates. It <sup>will</sup> combines these and other scientific disciplines to provide the best possible understanding of the anticipated courses of events during the conduct of an activity. It <sup>will</sup> incorporates new techniques such as logic tree analytical methodologies,<sup>14</sup> mathematical expressions of logic,<sup>15</sup> and events sequencing displays.<sup>16</sup> The ~~validation~~ <sup>evaluation</sup> of events sequences developed during a risk analysis is one of its most constructive features; these displays focus disagreements on specific uncertainties, rather than vague rhetorical arguments

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Not surprisingly, most of the early progress in developing risk analysis methods and technologies flowed from the nuclear and space activities. For example, fault tree methods<sup>17</sup> and one of the earliest probabilistic safety studies were developed to meet military aerospace needs.<sup>18</sup> Farmer's work during the 60's in the nuclear field was also noteworthy in bringing some of the ideas together into a decision making framework.<sup>19</sup> Another study examined the dangers of an orbiting nuclear power generator to the public.<sup>20</sup> Another looked at marine risks.<sup>21</sup>

The technology was building steadily.

#### RISK ANALYSIS: WHAT'S HAPPENING NOW?

In 1971, the National Transportation Safety Board, in the first public proposal of its kind by a Federal agency dealing with ~~risk analysis~~,<sup>22</sup> recommended the adoption of a risk-based approach to certain safety regulations. An exploratory forum on Risk Concepts in dangerous goods regulations, sponsored by the Transportation Association of America in June of 1971, provided insights into some of the issues involved in such a change. There seemed to be concurrence that the approach was desirable, but technology was not yet available to implement the approach.<sup>23</sup> That is the situation which prevails widely in many quarters to this day. However, risk analyses are being used for decisions in numerous areas. The following examples are illustrative of this trend.

~~In transportation,~~ The Department of Defense used risk analyses to identify and evaluate routes and methods of shipment for biological weapons transport.<sup>24</sup> A risk analysis has been ~~considered~~ <sup>used</sup> as evidence in litigation.<sup>25</sup> Risk analyses have been used for determining building safety levels in earthquake-prone areas,<sup>26</sup> for land use decision guidance,<sup>27</sup> for facility siting decisions,<sup>28</sup> for environmental impact assessments,<sup>29</sup> for the determination of the transportation safety of alternative forms of a hazardous material,<sup>30</sup> for the comparative assessment of the safety of different activities,<sup>31</sup> and for the establishment of priorities for safety program efforts.<sup>32</sup> They have been used at the Federal and State levels in the LNG importation risk assessment disputes.<sup>33,34</sup> The US Coast Guard is contracting for a Marine Safety Systems Management study, that will incorporate a review of risk analysis technology and its application to the Coast Guard's risk management needs in several of its functional and regulatory areas.<sup>35</sup> A number of analytical methods have been incorporated into a publication on risk management for the former Atomic Energy Commission.<sup>36</sup> The US Coast Guard has developed systems for assessing the damage from certain marine spills.<sup>37</sup> These are some of the many activities completed or now in progress in the risk analysis field.

To support these risk analyses, new data are being developed. For example, the Standard Transportation Commodity Code used by the railroad industry for accumulating traffic flow data was changed in 1976 for safety data purposes. A special series of codes was established to record the

substances that are subjected to safety regulation under 49CFR100-179, to differentiate them from unregulated commodities.<sup>38</sup> These data will provide meaningful exposure data for the exposure component of the risk analyses of dangerous chemicals moving by rail.

The Department of Transportation's Materials Transportation Bureau announced in June, 1976<sup>39</sup> that it intends "to undertake the task of formalizing, into a definite methodology and format, safety analyses which will be used in rulemaking and exemptions." The guidelines resulting from this undertaking will also contribute to increased use of risk analyses to answer specific safety questions. When completed, the Coast Guard's study<sup>40</sup> should also provide additional guidelines for risk analyses.

The risk perspectives are influencing other fields in some unusual ways. One must be mentioned. It was described in the National Observer recently.<sup>41</sup> A computer program has been developed, based on a statistical "risk of death" analysis, by which one's expected longevity can be examined, taking into account certain behavioral and life style factors of the individual. By inputting your factors, you can get a reading that tells you if you can expect to die before or after the national averages. This leads me into some speculations about what lies ahead.

#### RISK ANALYSIS: WHAT'S COMING?

The American public is becoming better acquainted with probabilistic estimates of future occurrences. One example is the daily exposure to the "chance of rain" expressed in probabilistic terms. Another is the life expectancy data. Public debate about energy projections and the controls over carcinogens at all levels also increases this recognition of the probabilistic nature of our assessments of the future. Problems such as the trade-offs between fire and cancer risks involved in the tris 2,3-dibromopropyl phosphate treatment of children's sleepware add to this public understanding.<sup>42</sup> The public seems receptive to looking at these problems in terms of risk trade-offs.

As these trade-offs are defined by risk analyses, some present value judgments may be modified. For example, if we eliminate all chemically-induced deaths, what would be the effect on our present average life span of 72.5 years? If we can eliminate highway accidents as a cause of death, our life expectancy might increase by about .55 years.<sup>43</sup> Would it increase by 1 minute, 1 hour, 1 day, 1 week, 1 year or what if we eliminate "chemical deaths" completely? Structuring the trade-offs this way shows the problem with a simple "body count" approach for establishing safety decision value judgments. The "lives saved" is misleading, because no one's life is "saved" -- the only true effect of the safety and health programs is that the longevity of life is increased and the mode of death may be shifted. And these effects are stimulating other interesting reappraisals,<sup>44</sup> questioning the value of added life.

Risk-based decisions that will be spawned by the results of risk analysis efforts will probably affect each of us in some other ways. If you are a technical safety specialist, you will have to work hard to stay abreast of the new technology, or risk obsolescence. If you are a public official, you will be forced to shift your attention increasingly from technical matters to a better understanding of value conflicts and the processes for their resolution in risk assessment and regulatory decisions. If you are a manager, you will have a method for identifying your alternative safety management objectives, and be better able to audit performance, but your value judgments -- and their consequences -- will become more visible. This will compel increased attention to the identification of possible

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adverse or harmful consequences over the entire life cycle of your outputs. If you are in the accident investigation/prevention business, you will have to adapt your efforts and outputs to satisfy the needs for understanding accident processes and health-harming mechanisms, on which risk analyses will be structured.<sup>45</sup> If you are a chemical worker, you should be able to look forward to fewer adverse "surprises," but you may be faced with more difficult value trade-offs involving life style versus longevity.<sup>46</sup> If you are a citizen, you can probably look forward to an increased life span, but shifting modes of death and, perhaps, changing life styles. If you are injured, risk-based approaches will probably change the way you will be compensated.<sup>47</sup> If you practice law, look for changes in the legal processes to reflect changes in societal perspectives of risk taking, accident deterrence and compensation.<sup>48</sup> If you are a transportation design engineer, be prepared to adapt your designs to engineering parameters for accidents.<sup>49</sup> *Your clients will have to abandon their biased views*

This is a time of change. Each professional would be well advised to explore the ramifications of the changes that will occur from the adaptation of risk analyses to safety and health problems, from his or her own perspectives. It is an approach whose time is here.

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